

REMARKS

These remarks are in response to the Final Office Action mailed July 25, 2007. Claim 56 has been canceled without prejudice to Applicants' right to prosecute the canceled subject matter in any divisional, continuation, continuation-in-part, or other application. Claim 49 has been amended to incorporate a portion of the preamble of claim 79 and the subject matter of claim 56. Thus, the subject matter incorporated into claim 49 was previously searched and does not introduce matter requiring an additional search.

I. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH (Written Description)

Claims 56-59 and 96-97 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. The claims allegedly contain subject matter that is not supported by the specification as filed. Applicants respectfully traverse this rejection.

In particular, the Office Action appears to allege that the term, "independently validated normal control" or "validated control" (of any kind) is not supported by the specification as filed. The language in the claims is fully supported by the specification as filed. For example, "normal controls," and "validated normal controls" as set forth in Claim 49, and dependent claims, is supported at paragraphs [0009]-[0010] and [0027]-[0031]. In fact, the phrase, "validated as normal controls," can be found in paragraph 27 to described the expression profiles:

In FIG. 2B, the results of biopsy tissue determined to be normal by histological evaluation taken from patients known to have CRC are compared to biopsy tissue from individuals **validated as normal controls**.

Accordingly, the statement, "The instant claims now recite limitations, which were not clearly disclosed in the specification as filed. . ." (see the Final Office Action at page 7, lines 5-7), appears to be in error. Furthermore, the attached Declaration indicates that one of skill in the art would recognize a "normal control" as used in the instant claims.

The Office Action also appears to allege that the phrase, ". . . identifies the subject as a candidate for the management of colorectal cancer and colorectal

polyps," is not supported by the application as filed. The specification, including the claims as originally filed, support the claimed invention as it pertains to identifying a subject as a "candidate for the management of colorectal cancer and colorectal polyps." For example, original claims 1, 7, 8, 9, 11 and 16 support the pending claims.

Applicants respectfully submit that the specification, as filed, including the claims and figures support the pending claims. The written description for the terms "validated normal controls" and "normal control" are supported in the specification as filed. The written description of "management of colorectal cancer and colorectal polyps" is supported in the specification and claims as filed. Accordingly, Applicants respectfully request withdrawal of the rejection.

II. REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH (ENABLEMENT)

Claims 49, 51-64, 79, 81-88 and 96-97 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The claims allegedly contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

The Final Office alleges,

Given that the state of the prior art was underdeveloped at the time of Applicant's filing, one of ordinary skill in the art would have relied to a larger extent upon the information disclosed in Applicant's specification. Here Applicant's arguments are also found unpersuasive because, while Applicant point to support in the specification to show that differences in gene expression were observed for panels of biomarkers in the context of normal and diseased tissue in both a mouse MIN model of colorectal polyps and in human specimens, the biomarker panels are not comprised of the same biomarkers recited in the claims.

(Final Office Action at page 11).

The claimed invention, as filed, comprised measuring a plurality of markers (e.g., SEQ ID NOs:1-22). This included IL-8, COX2 and SAA1 (e.g., SEQ ID NO:1, 2

and 5, respectively, and variants thereof). Furthermore, original claim 49 recited, ". . . a panel of biomarkers comprising at least two polynucleotides from SEQ ID NOs 1-5. . . ." As the Examiner will recognize, SEQ ID NOs; 1, 2 and 5 were included in the claimed invention, these elements are currently pending in the claims before the Examiner. However, it appears the Examiner is attempting to limit the claimed invention to certain specific examples of the specification in view of a broader disclosure (*i.e.*, the specific markers measured with the figures), this the Office should not do.

The attached 1.132 Declaration by Dr. Nancy Lee provides evidence, in addition to that in the specification, that measurement of IL-8, COX2 and SAA1 ("at least two from SEQ ID NOs 1-5") are changed (*e.g.*, increased) relative to controls. Thus, the application as filed contemplates and claims that a change in at least two biomarkers selected from SEQ ID NOs: 1-5 (*i.e.*, including IL-8, COX2 and SAA1) are indicative of colorectal cancer or polyps. Furthermore, the data presented in the specification, as filed, and in the attached Declaration demonstrate the invention as it relates to the claimed biomarkers and those subject to restriction in the present application. The Declaration further demonstrates, consistent with the original disclosure and claims, that PPAR- α and PPAR- γ change expression compared to normal control.

The claimed invention as filed is fully enabled by the specification. The specification teaches that measurement of biomarkers selected from SEQ ID NOs 1-22, including SEQ ID NOs: 1, 2, 5, 15 and 16 (IL-8, COX2, SAA1, PPAR- α and PPAR- γ) can be used to identify a subject having or at risk of having colorectal cancer or polyps.

For at least the foregoing reasons, Applicants respectfully request withdrawal of the pending rejections and request allowance of the claimed subject matter.

Applicants respectfully request that if there should be any questions regarding the foregoing amendments or remarks that the Examiner call the undersigned. The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment of fees to Deposit Account No. 02-4800.

Respectfully submitted,

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